DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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ACON LABORATORIES, INC.
QIYI XIE
SR. STAFF REGULATORY AFFAIRS & CLINICAL AFFAIRS
10125 MESA RIM ROAD
SAN DIEGO CA 92121

September 17, 2015

Re: K142543
Trade/Device Name: Mission® Urinalysis Reagent Strips,
Mission® Liquid Urine Controls,
Mission® Liquid Diptube Urine Controls,
Mission® U120 Ultra Urine Analyzer
Regulation Number: 21 CFR 862.1340
Regulation Name: Urinary glucose (nonquantitative) test system
Regulatory Class: II
Product Code: JIL, CDM, CEN, JIN, JIO, JIR, JJB, JMT, JRE, LJX, JMA, JJW, KQO
Dated: March 25, 2015
Received: March 26, 2015

Dear Qiyi Xie:

This letter corrects our substantially equivalent letter of May 11, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142543

Device Name
Mission® Urinalysis Reagent Strips
Mission® U120 Ultra Urine Analyzer
Mission® Liquid Urine Controls, Mission® Liquid Diptube Urine Controls

Indications for Use *(Describe)*
The Mission® U120 Ultra Urine Analyzer is intended for use in conjunction with the Mission® Urinalysis Reagent Strips for the semi-quantitative detection of the following analytes in urine: Glucose, Bilirubin, Ketone (Acetoacetic Acid), Specific Gravity, pH, Blood, Protein, Urobilinogen, Leukocytes and Ascorbic Acid as well as the qualitative detection of Nitrite.

The instrument is intended for point-of-care, in vitro diagnostic use only. The measurement can be used in general evaluation of health, and aids in the diagnosis and monitoring of metabolic or systemic diseases that affect kidney function, endocrine disorders and diseases or disorders of the urinary tract. It is intended for professional use only.

The Mission® Liquid Urine Controls and Mission® Liquid Diptube Urine Controls are assayed urine controls, intended for use in validating the precision of analyzer reading of urinalysis for one or more of the following analytes: Ascorbic acid, Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes. It is intended for professional in vitro diagnostic use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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7. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The Assigned 510(k) number is K142543

Submitter's Identification:

ACON Laboratories, Inc.
10125 Mesa Rim Road
San Diego, California 92121
Tel.: 858-875-8019
Fax: 858-875-8011

Date Prepared: May 11, 2015

Contact Person:

Qiyi Xie
Senior Staff, Clinical & Regulatory Affairs
Email: qxie@aconlabs.com

Proprietary Name of the Device:

Mission® Urinalysis Reagent Strips
Mission® U120 Ultra Urine Analyzer
Mission® Liquid Urine Controls
Mission® Liquid Diptube Urine Controls

Common Name:

Urine Chemistry Analyzer

Urinalysis Controls (Assayed and Unassayed)

Classification Name:

Class II §21 CFR § 862.1340 Urinary Glucose (Non-Quantitative) Test System

Class I §21 CFR 862.2900, Automated Urinalysis System

Class I, reserved §21 CFR 862.1660, Quality control material (assayed and unassayed)

Predicate Device:

ACON Urinalysis Reagent Strips, ACON U120 Urine Analyzer
ACON Laboratories Inc.
10125 Mesa Rim Road
San Diego, CA 92121
510(k) Number: K070929

Mission Liquid Urine Control, Mission Liquid Diptube Urine Control
ACON Laboratories Inc.
10125 Mesa Rim Road
San Diego, CA 92121
510(k) Number: K103387

Device Name: Mission® Urinalysis Reagent Strips, Mission® U120 Ultra Urine Analyzer
Mission® Liquid Urine Controls, Mission® Liquid Diptube Urine Controls

Regulation Description	Product Code	Device Class	Regulation
Occult blood test	JIO	II	21 CFR § 864.6550
Urinary glucose (non-quantitative) test system	JIL	II	21 CFR § 862.1340
Urinary protein or albumin (non-quantitative) test system	JIR	I	21 CFR § 862.1645
Urinary bilirubin and its conjugates (non-quantitative) test system	JJB	I	21 CFR § 862.1115
Ketones (non-quantitative) test system	JIN	I	21 CFR § 862.1435
Leukocyte peroxidase test	LJX	I	21 CFR § 864.7675
Nitrite (non-quantitative) test system	JMT	I	21 CFR § 862.1510
Urinary pH (non-quantitative) test system	CEN	I	21 CFR § 862.1550
Refractometer for clinical use (specific gravity)	JRE	I	21 CFR § 862.2800
Urinary urobilinogen (non-quantitative) test system	CDM	I	21 CFR § 862.1785
Ascorbic acid test system	JMA	I	21 CFR § 862.1095
Quality control material (assayed and unassayed)	JJW	I, reserved	21 CFR § 862.1660
Automated urinalysis system	KQO	I	21 CFR § 862.2900

Device Description:

The Mission® U120 Ultra Urine Analyzer is a reflectance photometer that analyzes the intensity and color of light reflected from the reagent areas of a urinalysis reagent strip. Without a urine analyzer, users must visually compare the reagent areas of the strip to a color chart using the naked eye. Mission® U120 Ultra Urine Analyzer also features data management and report generation capabilities.

Intended Use:

The Mission® U120 Ultra Urine Analyzer is intended for use in conjunction with the Mission® Urinalysis Reagent Strips for the semi-quantitative detection of the following analytes in urine: Glucose, Bilirubin, Ketone (Acetoacetic Acid), Specific Gravity, pH, Blood, Protein, Urobilinogen, Leukocytes and Ascorbic Acid as well as the qualitative detection of Nitrite.

The instrument is intended for point-of-care, in vitro diagnostic use only. The measurement can be used in general evaluation of health, and aids in the diagnosis and monitoring of metabolic or systemic diseases that affect kidney function, endocrine disorders and diseases or disorders of the urinary tract. It is intended for professional use only.

The Mission® Liquid Urine Controls and Mission® Liquid Diptube Urine Controls are assayed urine controls, intended for use in validating the precision of analyzer reading of urinalysis for one or more of the following analytes: Ascorbic acid, Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes. It is intended for professional in vitro diagnostic use only.

Tests Principles:

The Mission® U120 Ultra Urine Analyzer is a reflectance photometer that analyzes the intensity and color of light reflected from the reagent areas of a urinalysis reagent strip. Using a light emitting diode (LED) as the light source and a CMOS image sensor as a light sensor, the optical system reads the color change in the urine test strips after a sample is applied.

Urine Controls: The Mission® Liquid Urine Controls and Mission® Liquid Diptube Urine Controls are assayed urine controls, intended for use in validating the precision of analyzer reading of urinalysis for the following analytes: Ascorbic acid, Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes.

Technological Characteristics:

Feature	Mission® U120 Ultra Urine Analyzer
Methodology	Reflectance Photometer
Detection	CMOS Image Sensor
Chemistry	Mission® Urinalysis Reagent Strips
Throughput	Single Test Mode: 55 tests/hour Continuous Test Mode: 120 tests/hour
Memory	Last 2000 results
Strip Incubation Time	1 minute
PC Port	USB (data communications); (Not connect to PC) Bluetooth Wireless Standard RS232C Port
Capabilities	Internal thermal printer Barcode reader Connector External printer (optional) Barcode reader (optional) RJ45 Ethernet; (optional)
Available Languages on Screen	English and Spanish
Analyzer Operating Conditions	0-40ºC (32-104ºF); ≤85% Relative Humidity (non-condensing)
Strip Operating Conditions	15-30ºC (59-86ºF); 20-80% Relative Humidity (non-condensing)
Power Source	6 AA batteries with 100 tests/6 new batteries; 100- 240 VAC(adapter), (50-60

	Hz± 1HZ)
Weight	≤1.66 kg (3.65 lb) without batteries or power supply
Dimensions (L X W X H)	26.0 (L) x 15.0 (W) x 17.5 (H) cm (10.2”x 5.9”x 6.9”)
Display Dimensions (L X W)	Large touch screen Color LCD TFT 640x480, 11.7 (W) x 8.8 (H) cm

Substantial Equivalence:

The Mission® U120 Urinalysis Reagent Strips and the Ultra Urine Analyzer is substantially equivalent to the ACON Urinalysis Reagent Strips and the ACON U120 Urine Analyzer (K070929):

Item	Mission® Urinalysis Reagent Strips, Mission® U120 Ultra Urine Analyzer, Candidate Device	ACON Urinalysis Reagent Strips, ACON U120 Urine Analyzer, Predicate
Similarities		
Methodology	Reflectance Photometer	Reflectance Photometer
Principle	The U120 Urine Analyzer measures the intensity of the light reflected from the reagent areas of a urinalysis reagent strip.	The U120 Ultra Urine Analyzer measures the intensity of the light reflected from the reagent areas of a urinalysis reagent strip.
Chemistry	Mission® Urinalysis Reagent Strips	Mission® Urinalysis Reagent Strips
Analytes Detected	Leukocytes, Nitrite, blood (Occult), Glucose, Protein, Ketone, Specific Gravity, pH, Bilirubin, Urobilinogen and Ascorbic Acid	Leukocytes, Nitrite, blood (Occult), Glucose, Protein, Ketone, Specific Gravity, pH, Bilirubin, Urobilinogen and Ascorbic Acid
Strip Incubation Time	1 minute	1 minute
Available Languages on Screen	English and Spanish	English and Spanish

Analyzer Operating Conditions	0-40ºC (32-104ºF); ≤85% Relative Humidity (non-condensing)	0-40ºC (32-104ºF); ≤85% Relative Humidity (non-condensing)
Line Leakage Current	<0.5mA	<0.5mA
Differences		
Detection	The ACON U120 Urine Analyzer utilizes a photodiode to measure the intensity of light.	The Mission® U120 Ultra Urine Analyzer utilizes a CMOS image sensor to measure the intensity of light.
Throughput	Single Test Mode: 60 tests/hour Continuous Test Mode: 120 tests/hour	Single Test Mode: 55 tests/hour Continuous Test Mode: 120 tests/hour
Memory	Last 500 results	Last 2000 results
PC Port	Standard RS232C Port (cable not included)	Standard RS232C Port (cable not included), USB Port (cable not included); (Not connect to PC) Bluetooth Wireless
Capabilities	Internal heat sensitive printer (included) 25 Pin Parallel External Printer Port (not included) External printer (optional)	Internal thermal printer Barcode reader Connector External printer (optional) Barcode reader (optional) RJ45 Ethernet; (optional)
Power Source	220 Volts AC (±10%), 50 Hz (±1), 110 Volts AC (±10%), 60 Hz (±1), 110-230 Volts AC, 50/60 Hz	6 AA batteries with 100 tests/6 new batteries; 100- 240 VAC(adapter), (50-60 Hz± 1HZ)
Optimum Operating Conditions	15-30ºC (59-86ºF); ≤75% Relative Humidity (non-condensing)	15-30ºC (59-86ºF); 20-80% Relative Humidity (non-condensing)
User Interface	MKB Key based UI	Touch Screen based UI
Weight	2.6 Kg (5.73 lbs.)	≤1.66 kg (3.65 lbs.) without batteries or power supply
Dimensions (L X W X H)	27.1 (L) x 26.5 (W) x 14.6 (H) cm	26.0 (L) x 15.0 (W) x 17.5 (H) cm

Display Dimensions (L X W)	240x128 blue and white, 10.6 (W) x 2.8 (H) cm	Large touch screen Color LCD TFT 640x480, 11.7 (W) x 8.8 (H) cm
Appearance		

Mission® Liquid Urine Controls and Mission® Liquid Diptube Urine Controls are substantially equivalent to ACON's 510k cleared - Mission® Liquid Urine Controls and Mission® Liquid Diptube Urine Controls (K103387)

Feature	Mission® Liquid Urine Controls, Mission® Liquid Diptube Urine Controls	Mission® Liquid Urine Controls, Mission® Liquid Diptube Urine Controls (K103387)
Intended/Indications for Use	For use as an assayed quality control urine to monitor the precision of urinalysis test procedures for the analytes listed in the package insert. The Mission® Liquid Urine Control and Mission® Liquid Diptube Urine Control are for use with the Mission® Urinalysis Reagent Strips and Mission U120 Ultra Urine Analyzer	For use as an assayed quality control urine to monitor the precision of urinalysis test procedures for the analytes listed in the package insert. The Mission® Liquid Urine Control and Mission® Liquid Diptube Urine Control are for use with the Mission® Urinalysis Reagent Strips and Mission U120 Urine Analyzer (K070929)
Levels	2	Same
Form	Liquid	Same

Analytes	Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes, and Ascorbic Acid	Same
Storage	2 to 8°C	Same
Matrix	Liquid Matrix Solution	Same
Open Vial	24 months at 2-8°C 30 Days at 15-30°C	Same
Packaging Configuration	Dropper, diptube	Same
Shelf Life	24 months at 2-8°C	Same

Discussion of Clinical Tests Performed:

Clinical studies were conducted using the Mission® U120 Ultra Urine Analyzer and Mission® Urinalysis Reagent strips. The purpose of the study was to evaluate the performance of Mission® Urinalysis Reagent strip read by Mission® U120 Ultra Urine Analyzer compared to the predicate: Mission® Urinalysis Reagent strip read by ACON U120 Urine Analyzer (K070929); and to observe if there is any problem/issue with operation of the Mission® Urinalysis Reagent strip / Mission® U120 Ultra Urine Analyzer when they are placed in the hands of the intended user.

Approximately 120 patient urine specimens were randomly collected from patients at each of 3 clinical sites, and tested by 3 intended users at each site (total of 9 users for all 3 sites) Each specimen was tested by Mission® Urinalysis Reagent strip read with Mission® U120 Ultra Urine Analyzers and Mission® Urinalysis Reagent strip read with Mission® U120 Urine Analyzers. Each intended user tested approximately the same number of specimens at each site. The study period at each site last over 3 months. In order to evaluate the performance with the analyte covering the measuring range, few contrived urine specimens were tested at each site following the study protocol.

Additional study was carried out at 2 sites in US; a POC site and a specialty care office for inclusion of positive samples for the Nitrite, Urobilinogen, Ketone and Bilirubin analytes.

Below is the summary of the specimens tested at all sites combined:

Test	Comparative Method	N (including contrived samples)	% Exact Agreement	% Within one level Agreement
Leukocyte	U120 Ultra vs U120 Urine Analyzer	468	95.3% (446/468)	100% (468/468)
Nitrite	U120 Ultra vs U120 Urine Analyzer	451	100% (451/451)	100% (451/451)
Uro	U120 Ultra vs U120 Urine Analyzer	426	93.4% (398/426)	100% (426/426)
Pro	U120 Ultra vs U120 Urine Analyzer	468	92.7% (434/468)	100% (468/468)
pH	U120 Ultra vs U120 Urine Analyzer	468	86.8% (406/468)	100% (468/468)
Blo	U120 Ultra vs U120 Urine Analyzer	468	93.8% (439/468)	100% (468/468)
SG	U120 Ultra vs U120 Urine Analyzer	468	85.5% (400/468)	100% (468/468)
Ketone	U120 Ultra vs U120 Urine Analyzer	458	96.4% (446/458)	100% (458/458)
Bil	U120 Ultra vs U120 Urine Analyzer	450	97.4% (444/450)	100% (450/450)
Glu	U120 Ultra vs U120 Urine Analyzer	468	95.7% (448/468)	100% (468/468)
ASC	U120 Ultra vs U120 Urine Analyzer	468	90.0% (421/468)	100% (468/468)

These clinical study and statistical data demonstrated that the intended user can follow the product instruction and obtain comparable instrument read results when using the Mission®U120 Ultra Urine Analyzer and a predicate Analyzer. The clinical study results indicate that the Mission®U120 Ultra Urine Analyzer is substantially equivalent to the legally marketed device ACON U120 Urine Analyzer.

Discussion of Performance Tests Performed:

The performance characteristics of the Mission® U120 Ultra Urine Analyzer to read Mission® Urinalysis Reagent Strips were verified by Precision study, Interference study, Temperature flex study, voltage flex study, SG flex study, pH flex study, Humidity flex study, sensitivity study, stability study, electrical safety testing and EMC testing. Laboratory testing results indicate that the Mission® U120 Ultra Urine Analyzer is robust and can perform satisfactorily when used according to the "Indication for Use" statement specified in the Instruction Manual and Package Insert of the device.

Sensitivity Study:

The sensitivity of the Mission® Urinalysis Reagent Strips was determined in combination of the Mission® U120 Ultra Urine Analyzer. The low and high end range of sensitivity for Mission® Urinalysis Reagent Strips tested by Mission® U120 Ultra is listed in table below.

Analyte	Color block	Low end sensitivity	High end sensitivity
Ascorbic Acid	40 mg/dL	30 mg/dL	>40 mg/dL
	20 mg/dL	15 mg/dL	27.5 mg/dL
	10 mg/dL	5 mg/dL	13.5 mg/dL
	0 mg/dL	0 mg/dL	4.5 mg/dL
Glucose	1000 mg/dL	750 mg/dL	>1000 mg/dL
	500 mg/dL	375 mg/dL	675 mg/dL
	250 mg/dL	192.5 mg/dL	337.5mg/dL
	100 mg/dL	50 mg/dL	175 mg/dL
	0 mg/dL	0 mg/dL	45mg/dL
Bilirubin	4 mg/dL	3 mg/dL	>4 mg/dL
	2 mg/dL	1.5 mg/dL	2.7 mg/dL
	1 mg/dL	0.4 mg/dL	1.35 mg/dL
	0 mg/dL	0 mg/dL	0.35 mg/dL
Ketone	80 mg/dL	60 mg/dL	> 80 mg/dL
	40 mg/dL	27.5 mg/dL	54 mg/dL
	15 mg/dL	11 mg/dL	24.75 mg/dL

	5 mg/dL	2.5 mg/dL	10 mg/dL
	0 mg/dL	0 mg/dL	2.25 mg/dL
Specific Gravity	1.000~1.030	1.000	1.030
Blood	200Ery/μL	140 Ery/μL	>200 Ery/μL
	80 Ery/μL	52.5 Ery/μL	126 Ery/μL
	25 Ery/μL	12.5 Ery/μL	47.25 Ery/μL
	10 Ery/μL	5 Ery/μL	15.75 Ery/μL
	0 Ery/μL	0 Ery/μL	4.5 Ery/μL
pH	5.0~9.0	5.0	9.0
Protein	300 mg/dL	200 mg/dL	>300 mg/dL
	100 mg/dL	65 mg/dL	180 mg/dL
	30 mg/dL	22.5 mg/dL	58.5 mg/dL
	15 mg/dL	7.5 mg/dL	20.25 mg/dL
	0 mg/dL	0 mg/dL	6.75 mg/dL
Urobilinogen	8 mg/dL	6 mg/dL	>8 mg/dL
	4 mg/dL	3 mg/dL	5.4 mg/dL
	2 mg/dL	1.5 mg/dL	2.7 mg/dL
	1 mg/dL	0.6 mg/dL	1.35 mg/dL
	0.2mg/dL	0 mg/dL	0.54mg/dL
Nitrite	0.1 mg/dL	0.05mg/dL	>0.1 mg/dL
	0 mg/dL	0 mg/dL	0.045 mg/dL
Leukocyte	500 Leu/μL	312.5 Leu/μL	>500 Leu/μL
	125 Leu/μL	97.5 Leu/μL	281.25 Leu/μL
	70 Leu/μL	42.5 Leu/μL	87.75 Leu/μL
	15 Leu/μL	9 Leu/μL	38.25 Leu/μL
	0 Leu/μL	0 Leu/μL	8.25 Leu/μL

Precision Study:

The reproducibility of the Mission® U120 Ultra Urine Analyzer was evaluated using 3 levels of Control Solutions. The target concentration of the analyte in each control solution was

confirmed with Siemens reagent strips read by Clinitek Status urine analyzer and Mission® Urinalysis Reagent Strip read by ACON U120 urine analyzer. Each control solution was tested with one lot of strip in duplicates per run, 2 runs each day by one operator for 20 days. Second operator performed the test following the same protocol with second lot and second analyzer. A total of160 strips were used for each concentration tested (2 strips x 2 run x 20 days x 2 operators= 160 strips). The precision for each device was 100% exact agreement. The results are summarized as below.

Control	Analyte	Agreement at same block	Agreement within +/- one block
Level 1	Ascorbic acid	100% (160/160)	100% (160/160)
	Glucose	100% (160/160)	100% (160/160)
	Bilirubin	100% (160/160)	100% (160/160)
	Ketone	100% (160/160)	100% (160/160)
	S.G.	95.0% (152/160)	100% (160/160)
	Blood	100% (160/160)	100% (160/160)
	pH	97.5% (156/160)	100% (160/160)
	Protein	100% (160/160)	100% (160/160)
	Urobilinogen	100% (160/160)	100% (160/160)
	Nitrite	100% (160/160)	100% (160/160)
	Leukocyte	100% (160/160)	100% (160/160)
Level 2	Ascorbic acid	96.9% (155/160)	100% (160/160)
	Glucose	98.1% (157/160)	100% (160/160)
	Bilirubin	97.5% (156/160)	100% (160/160)
	Ketone	98.1% (157/160)	100% (160/160)
	S.G.	95.6% (153/160)	100% (160/160)
	Blood	98.8% (158/160)	100% (160/160)
	pH	96.9% (155/160)	100% (160/160)
	Protein	96.9% (155/160)	100% (160/160)
	Urobilinogen	97.5% (156/160)	100% (160/160)
	Nitrite	100% (160/160)	100% (160/160)
	Leukocyte	99.4% (159/160)	100% (160/160)

Level 3	Ascorbic acid	100% (160/160)	100% (160/160)
	Glucose	98.8% (158/160)	100% (160/160)
	Bilirubin	98.1% (157/160)	100% (160/160)
	Ketone	96.3% (154/160)	100% (160/160)
	S.G.	94.4% (151/160)	100% (160/160)
	Blood	99.4% (159/160)	100% (160/160)
	pH	98.1% (157/160)	100% (160/160)
	Protein	100% (160/160)	100% (160/160)
	Urobilinogen	98.1% (157/160)	100% (160/160)
	Nitrite	100% (160/160)	100% (160/160)
	Leukocyte	98.1% (157/160)	100% (160/160)

Precision Studies were also performed by testing each level of control solution by a single operator in 20 replicates per run per day with each lot on U120 Ultra. Operator 2 and operator 3 followed the same procedure with different lots of strips on different Mission® U120 Ultra Analyzers. A total of 180 strips were used for each concentration tested (20 strips x 3 lots x 3 analyzers (3 operators) x 1day = 180 strips. The precision for each device was 100% exact agreement. The results are summarized as below.

Control Level	Analyte	Agreement at same block	Agreement within +/- one block
Level 1	Ascorbic acid	100% (180/180)	100% (180/180)
	Glucose	100% (180/180)	100% (180/180)
	Bilirubin	100% (180/180)	100% (180/180)
	Ketone	100% (180/180)	100% (180/180)
	S.G.	95.6% (172/180)	100% (180/180)
	Blood	100% (180/180)	100% (180/180)
	pH	97.2% (175/180)	100% (180/180)
	Protein	100% (180/180)	100% (180/180)
	Urobilinogen	100% (180/180)	100% (180/180)
	Nitrite	100% (180/180)	100% (180/180)
	Leukocyte	100% (180/180)	100% (180/180)

Level 2	Ascorbic acid	97.8% (176/180)	100% (180/180)
	Glucose	96.7% (174/180)	100% (180/180)
	Bilirubin	97.2% (175/180)	100% (180/180)
	Ketone	97.2% (175/180)	100% (180/180)
	S.G.	92.2% (166/180)	100% (180/180)
	Blood	95.6% (172/180)	100% (180/180)
	pH	93.9% (169/180)	100% (180/180)
	Protein	97.2% (175/180)	100% (180/180)
	Urobilinogen	95.5% (172/180)	100% (180/180)
	Nitrite	100% (180/180)	100% (180/180)
	Leukocyte	98.3% (177/180)	100% (180/180)
Level 3	Ascorbic acid	98.9% (178/180)	100% (180/180)
	Glucose	93.3% (168/180)	100% (180/180)
	Bilirubin	97.2% (175/180)	100% (180/180)
	Ketone	97.8% (176/180)	100% (180/180)
	S.G.	97.8% (176/180)	100% (180/180)
	Blood	96.7% (174/180)	100% (180/180)
	pH	93.9% (169/180)	100% (180/180)
	Protein	98.9% (178/180)	100% (180/180)
	Urobilinogen	97.8% (176/180)	100% (180/180)
	Nitrite	100% (180/180)	100% (180/180)
	Leukocyte	97.8% (176/180)	100% (180/180)

Interference Substances:

The effect of interfering substances commonly found in urine on Mission® Urinalysis Reagent Strips when read by Mission® U120 Ultra Urine Analyzers was studied by preparing 3 levels of controls for each analyte present in the urine and tested with one urine strip on one analyzer following the product insert. Total 3 lots of urine test strips and 3 urine analyzers were used for the study. The following substances were found to interfere with the testing results.

Reagent pad	Interference substances	Conc.	U120 Ultra analyzer
Glucose	Ascorbic acid	≥25 mg/dL	False decreased results
	Ketone (Acetoacetate)	≥100 mg/dL	False decreased results
Bilirubin	Ascorbic acid	≥50 mg/dL	False decreased results
	Blood	≥5%	False increased results
Ketone	Blood	≥5%	False increased results
Specific gravity	Protein (Albumin)	≥300 mg/dL	False increased results
Blood	Ascorbic acid	≥50 mg/dL	False decreased results
Urobilinogen	Nitrite	≥10 mg/dL	False decreased results
Protein	Hemoglobin	≥20 mg/dL	False increased results
	Blood	≥0.05%	False increased results
Urobilinogen	Blood	≥5%	False increased results
Nitrite	Ascorbic acid	≥30 mg/dL	False decreased results
	Blood	≥1%	False increased results
Leukocyte	Glucose	≥2000 mg/dL	False decreased results
	Blood	≥0.05%	False increased results

Temperature Flex Study:

The optimal temperature range for performing the test of Mission® Urinalysis Reagent Strip by Mission® U120 Ultra Urine Analyzer was validated at temperature 2°C to 45°C by performing the test at different temperatures in 5 replicates for each sample.

Humidity Flex Study:

50 strips were stored in different humidity environments and tested with Mission® U120 Ultra Urine Analyzer at different time points. The time that the strips was stable after exposed to the different storage condition is listed in the following table:

Reagent strips	Humidity of the storage conditions	The time that the strips was stable after exposed to the different storage condition
Ascorbic acid	<20%	>24h

	30-50%	>24h
	60-70%	>24h
	>80%	>24h
Glucose	<20%	>24h
	30-50%	>24h
	60-70%	8h
	>80%	4h
Bilirubin	<20%	>24h
	30-50%	>24h
	60-70%	>24h
	>80%	>24h
Ketone	<20%	>24h
	30-50%	16h
	60-70%	2h
	>80%	2h
Specific Gravity	<20%	>24h
	30-50%	>24h
	60-70%	>24h
	>80%	>24h
Blood	<20%	>24h
	30-50%	>24h
	60-70%	16h
	>80%	4h
pH	<20%	>24h
	30-50%	>24h
	60-70%	>24h
	>80%	>24h
Protein	<20%	>24h
	30-50%	>24h
	60-70%	>24h
	>80%	>24h
Urobilinogen	<20%	>24h
	30-50%	>24h

	60-70%	>24h
	>80%	>24h
Nitrite	<20%	>24h
	30-50%	16h
	60-70%	1h
	>80%	0.5h
Leukocyte	<20%	>24h
	30-50%	>24h
	60-70%	>24h
	>80%	8h

Voltage Flex Study:

The voltage flex study was performed using Mission® Liquid urine control, Level 1(normal) and Level 2 (abnormal) on analyzers supplied with the following voltages: 86V, 100V and 264V. 220V was also tested as the baseline control condition. Three analyzers were turned on using each of the voltage, and tested to see if the analyzer works properly. The analyzers were tested three times under each voltage. Mission® U120 Ultra urine analyzer can operate properly under 86V, 100V and 264V, and the test results are comparable to those of the 220V baseline control results. In conclusion, the range from 86V to 264V is suitable for operation of the Mission® U120 Ultra urine analyzer.

pH Flex Study:

5 normal fresh urines were collected and mixed. The mixed urine was tested with Siemens Clinitek Status and ACON U120 urine analyzer to determine the concentrations in the pooled urine. The Leu, Nit, Uro, Pro, Blo, Ket, Bil, Glu and Asc in the pooled urine were negative with pH at 6.5 and SG at 1.010. The mixed urine samples were split into five aliquots (150 ml / each glass container). Adjust these five aliquots urine pH to 5, 6, 7, 8, 9 with 1M Hydrochloric acid aqueous and 1M Sodium hydroxide aqueous. Then spiked analytes to different concentration as control Level 1, Level 2 and Level 3 listed in the table. The concentrations of each analyte in the control at pH 6 were confirmed with 510(k) cleared Siemens Clinitek Status and U120 urine analyzer, the results were used as expected values. Test these control solutions

with Mission® Urinalysis Reagent strips by Mission U120 Ultra analyzer following the product inserts. 5 replicates were tested for each sample.

Sample pH from 5.0 to 9.0 does not affect the results of Urobilinogen, Ketone, Bilirubin, and Glucose tests. Sample pH>8 would generate false high results on Protein test. Sample pH>9 would generate false high results on Leukocyte and Specific Gravity test, and false low results on Nitrite, Blood, Ascorbic acid test.

Urine Controls Validation:

Value Assignment

Control value assignment for the Mission Liquid Urine Control and Mission Liquid Diptube Urine Control was done by testing Level 1 and Level 2 using the Mission Urinalysis Reagent Strips tested on the Mission U120 Ultra Urine analyzer. Three lots of strips and three analyzers were tested for three consecutive days by three operators. All results for level 1 were negative except for SG and pH which should be +/- 2 color blocks of target results and all results for level 2 showed positive results except for ascorbic acid.

Stability Studies

Accelerated, Real Time and Open Stability studies were performed to test the shelf life of Mission Liquid Urine Control and Mission Liquid Diptube Urine Control under different conditions. Accelerated stability study confirmed that the product is stable at 2-8℃ for 24 months when stored properly in unopened bottles. Real Time Stability study confirmed the shelf life of the controls is 24 month. Open Canister Stability study confirmed that the controls remain stable for up to 30 days at 15-30°C and 24months at 2-8°C after being opened.

Conclusion:

The laboratory testing results and clinical studies demonstrate that the Mission® U120 Ultra Urine Analyzer is safe, effective and easy-to-use and such is substantially equivalent to the ACON U120 Urine Analyzer (K070929), currently sold on the U.S. market for professional (point-of-care) testing.